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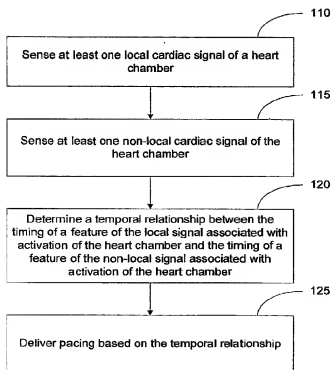
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(54) Title: LOCAL AND NON-LOCAL SENSING FOR CARDIAC PACING



(57) Abstract: Systems and methods for determining pacing timing intervals based on the temporal relationship between the timing of local and non-local cardiac signal features are described. A device includes a plurality of implantable electrodes electrically coupled to the heart and configured to sense local and non-local cardiac signals. Sense circuitry coupled to first and second electrode pairs senses a local cardiac signal via a first electrode pair and a non-local cardiac signal via a second electrode pair. Detection circuitry is used to detect a feature of the local signal associated with activation of a heart chamber and to detect a feature of the non-local signal associated with activation of the heart chamber. A control processor times delivery of one or more pacing pulses based on a temporal relationship between timing of the local signal feature and timing of the non-local signal feature.



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LOCAL AND NON-LOCAL SENSING FOR CARDIAC PACING

FIELD OF THE INVENTION

The present invention relates generally to cardiac pacing therapy, and more
5 specifically, to methods and systems for timing the delivery of pacing pulses based on local
and non-local sensing of cardiac signals.

BACKGROUND OF THE INVENTION

The healthy heart produces regular, synchronized contractions. Rhythmic
10 contractions of the heart are normally initiated by the sinoatrial (SA) node, which is a
group of specialized cells located in the upper right atrium. The SA node is the normal
pacemaker of the heart, typically initiating 60-100 heartbeats per minute. When the SA
node is pacing the heart normally, the heart is said to be in normal sinus rhythm.

Cardiac arrhythmia occurs when the heart rhythm is irregular or if the heart rate is
15 too slow or too fast. During an arrhythmic episode, the heart's pumping action may
become impaired and blood flow to peripheral tissues may be inadequate. Cardiac
arrhythmias have a number of etiological sources, including tissue damage due to
myocardial infarction, infection, or degradation of the heart's ability to generate or
synchronize the electrical impulses that coordinate contractions.

20 Bradycardia occurs when the heart rhythm is too slow. This condition may be
caused, for example, by impaired function of the SA node, denoted sick sinus syndrome,
or by delayed propagation or blockage of the electrical impulse between the atria and
ventricles. Bradycardia produces a heart rate that is too slow to maintain adequate
circulation.

25 When the heart rate is too rapid, the condition is denoted tachycardia. Tachycardia
may have its origin in either the atria or the ventricles. Tachycardia occurring in the atria
of the heart, for example, includes atrial fibrillation and atrial flutter. Both conditions are
characterized by rapid contractions of the atria. Besides being hemodynamically
inefficient, the rapid contractions of the atria may also adversely affect the ventricular rate.

30 Ventricular tachycardia occurs, for example, when electrical activity arises in the
ventricular myocardium at a rate more rapid than the normal sinus rhythm. Ventricular
tachycardia may quickly degenerate into ventricular fibrillation. Ventricular fibrillation is

a condition denoted by extremely rapid, uncoordinated electrical activity within the ventricular tissue. The rapid and erratic excitation of the ventricular tissue prevents synchronized contractions and impairs the heart's ability to effectively pump blood to the body, which is a fatal condition unless the heart is returned to sinus rhythm within a few minutes.

Implantable cardiac rhythm management systems have been used as an effective treatment for patients with serious arrhythmias, as well as for patients with conditions such as congestive heart failure. These systems typically include one or more leads and circuitry to sense signals from one or more interior and/or exterior surfaces of the heart. Such systems also include circuitry for generating electrical pulses that are applied to cardiac tissue at one or more interior and/or exterior surfaces of the heart. For example, leads extending into the patient's heart are connected to electrodes that contact the myocardium for sensing the heart's electrical signals and for delivering pulses to the heart in accordance with various therapies for treating arrhythmias.

Some implantable cardiac rhythm management systems include one or more endocardial leads which may include electrodes for both pacing and defibrillation. Such implantable cardiac rhythm management (CRM) systems are capable of delivering low energy pacing pulses to the heart at intervals sufficient to support the body's hemodynamic requirements. The CRM system may also deliver high-energy defibrillation shocks to the heart.

Cardiac pacing therapy involves the use of pacing timing intervals between pacing pulses delivered to various heart chambers. Appropriate specification of these and other timing intervals is desired to achieve optimal improvement of cardiac function. For the reasons stated above, and for other reasons stated below which will become apparent to those skilled in the art upon reading the present specification, there is a need in the art for methods and systems that provide for determination of timing intervals for cardiac pacing therapy. The present invention fulfills these and other needs.

SUMMARY OF THE INVENTION

The present invention is directed to systems and methods for determining pacing timing intervals based on the temporal relationship between the timing of local and non-

local cardiac signal features. One embodiment is directed to a method for delivery of pacing therapy. At least one local cardiac electrical signal and at least one non-local cardiac electrical signal are sensed using body-implantable electrodes. The method involves sensing for a feature of the local signal corresponding to activation of a heart chamber and sensing for a feature of the non-local signal corresponding to the activation of the heart chamber. Delivery of one or more pacing pulses is based on a temporal relationship between timing of the feature of the local signal and timing of the feature of the non-local signal.

Some implementations involve beat by beat determination of pacing timing intervals. In these implementations, sensing the local signal and sensing the non-local signal involves sensing these signals during a cardiac cycle. The delivery of pacing pulses for the cardiac cycle is based on a temporal relationship between the timing of features of the local signal and the non-local signal.

According to one aspect of the invention, timing the delivery of the pacing pulses involves determining an atrioventricular delay based on the temporal relationship between the local feature timing and the non-local feature timing. In one implementation, the local cardiac signal is sensed from a local atrial site. A local P-wave is detected from the local signal and a non-local P-wave is detected from the non-local signal. The delivery of the pacing pulses is timed based on the temporal relationship between the local P-wave and the non-local P-wave.

In another implementation, the local cardiac signal is sensed from a local atrial site. A local P-wave is detected from the local signal and a non-local P-wave is detected from the non-local signal. Timing delivery of the pacing pulses involves initiating the atrioventricular delay based on the detection of the local P-wave and ending the atrioventricular delay based on the detection of the non-local P-wave.

Various implementations of the invention involve delivery of trigger pacing. Pacing may be triggered to a single heart chamber or to contralateral heart chambers. For example, delivery of a pacing pulse may be triggered based on the timing of the non-local feature if the non-local feature is detected. If the non-local feature is not detected, the pacing pulse may be triggered based on the timing of the local feature. More specifically for atrial pacing, pacing may be triggered to one or more atria based on the timing of a

non-local P-wave if the non-local P-wave is detected. If the non-local P-wave is not detected, pacing may be triggered based on the timing of a local P-wave. For ventricular pacing, pacing may be triggered to one or more ventricles based on the timing of a non-local QRS complex if the non-local QRS complex is detected. If the non-local QRS complex is not detected, pacing may be triggered based on the timing of a local QRS complex.

Another embodiment of the invention is directed to an implantable cardiac rhythm management device. The implantable device includes a plurality of implantable electrodes electrically coupled to the heart. At least a first pair of the plurality of electrodes is configured to sense a local cardiac signal. At least a second pair of the plurality of electrodes is configured to sense a non-local cardiac signal. Sense circuitry is coupled to the first and second electrode pairs and is configured to sense a local cardiac signal via the first electrode pair and a non-local cardiac signal via the second electrode pair. Detection circuitry is configured to detect a feature of the local signal associated with activation of a heart chamber and to detect a feature of the non-local signal associated with activation of the heart chamber. A control processor times delivery of one or more pacing pulses based on a temporal relationship between timing of the local signal feature and timing of the non-local signal feature.

For example at least one electrode of the second pair of electrodes may comprise a ring electrode, a defibrillation coil, or a subcutaneous, non-intrathoracic electrode.

According to one aspect of the invention, the local signal feature comprises a local P-wave and the non-local signal feature comprises a non-local P-wave. The control processor is configured determine an atrioventricular delay based on the temporal relationship between the timing of the local P-wave and the timing of the non-local P-wave. The atrioventricular delay is used to time delivery of the one or more pacing pulses. According to various aspects, the control processor may be configured to determine the atrioventricular delay based on the temporal relationship between a beginning, end, or peak timing of the local P-wave and a beginning, end, or peak timing of the non-local P-wave.

According to one aspect of the invention, the control processor is configured to trigger pacing based on the timing of the non-local signal feature if the non-local signal

feature is detected and to trigger pacing based on the timing of the local signal feature if the non-local signal feature is not detected.

The pacing pulses may be delivered as part of a bradycardia pacing therapy, an atrioventricular pacing therapy and/or a resynchronization pacing therapy.

5 The above summary of the present invention is not intended to describe each embodiment or every implementation of the present invention. Advantages and attainments, together with a more complete understanding of the invention, will become apparent and appreciated by referring to the following detailed description and claims taken in conjunction with the accompanying drawings.

10

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A is a flow diagram illustrating a method of determining pacing timing in accordance with embodiments of the invention;

15 Figure 1B is a flow diagram illustrating a method for determination of a pacing timing interval based on the interval between features of the local and non-local signals in accordance with embodiments of the invention;

Figure 1C is a flow diagram illustrating trigger pacing based on local and non-local signals in accordance with embodiments of the invention;

20 Figures 2A-2B illustrate local and non-local cardiac signals which may be used for timing the delivery of pacing pulses in accordance with embodiments of the invention;

Figure 3 shows graphs of local and non-local signals illustrating the determination of an atrioventricular delay (AVD) in accordance with embodiments of the invention;

25 Figure 4 is a flow diagram illustrating a method for beat by beat adjustment of AVD based on P-waves detected from local and non-local signals of each cardiac cycle in accordance with embodiments of the invention;

Figure 5 is a graph illustrating determination of AVD for a cardiac cycle based on the local and non-local signal features of one or more previous cardiac cycles in accordance with embodiments of the invention;

30 Figure 6 is a flow diagram of a method for implementing triggered pacing with backup pacing in accordance with an embodiment of the invention;

Figure 7 illustrates a therapy device that may be used to time the delivery of cardiac pacing pulses based on local and non-local sensing in accordance with embodiments of the invention; and

Figure 8 is a block diagram depicting various components of a system that may be used to deliver pacing therapy with pacing timing implemented in accordance with
5 embodiments of the invention.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail below. It is to be understood, however, that the intention is not to limit
10 the invention to the particular embodiments described. On the contrary, the invention is intended to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS

15 In the following description of the illustrated embodiments, references are made to the accompanying drawings, which form a part hereof, and in which is shown by way of illustration, various embodiments in which the invention may be practiced. It is to be understood that other embodiments may be utilized, and structural and functional changes may be made without departing from the scope of the present invention.

20 Systems, devices or methods according to the present invention may include one or more of the features, structures, methods, or combinations thereof described hereinbelow. For example, a device or system may be implemented to include one or more of the advantageous features and/or processes described below. It is intended that such device or system need not include all of the features described herein, but may be implemented to
25 include selected features that provide for useful structures and/or functionality. Such a device or system may be implemented to provide a variety of therapeutic or diagnostic functions.

Mechanical contractions in the heart are triggered by waves of electrical depolarization that travel through the cardiac tissue. In a healthy heart, a depolarization
30 wave for each cardiac cycle is initiated at the sinoatrial node and travels through specialized fibers to the heart chambers to cause synchronized contractions of the heart

chambers. Due to disease, damage from myocardial infarction, and/or other degradation, the pathways and/or tissues involved in conduction of the depolarization wavefront may become compromised.

Pacemakers deliver electrical pacing pulses to the heart to produce contractions of the heart chambers in synchrony and at a rate sufficient to meet metabolic demand. Pacing
5 therapy involves the implementation of timing intervals between various events during a cardiac cycle. The timing intervals may be used to control the rate of heart chamber contractions and/or the synchrony between heart chamber contractions. For example, for patients whose intrinsic heart rate is too slow, pacing assists the heart in contracting at a
10 rate that is sufficient to provide blood flow to meet the patient's metabolic requirements. For patients suffering from congestive heart failure (CHF), cardiac pacing may be used to ensure that the contractions of the heart chambers occur in a timed sequence that improves heart function.

Pacemakers typically include cardiac electrodes that are in electrical contact with
15 the myocardium and sense local cardiac electrical signals. The electrodes are used to sense cardiac electrical signals, such as cardiac signals associated with intrinsic or evoked cardiac depolarization events. Pacemakers that stimulate the heart according to timing intervals based on sensed cardiac events are capable of producing cardiac cycles that more closely mimic the physiological operation of a normal heart.

20 A cardiac electrical signal provides information about the depolarization status of the heart. Local sensing of cardiac signals may be achieved via electrodes that make contact with the cardiac myocardium. Local sensing using an electrode in contact with the myocardial tissue yields signals that are most strongly representative of the activation signals that are present close to the site of the electrode. Non-local sensing of the cardiac
25 signals may be achieved via electrodes that are electrically coupled to, but do not make directed contact with, the myocardium. A sensed non-local cardiac activation signal is effectively a superposition of a number of activation signals occurring within the heart that are associated with a cardiac contraction.

In implantable pacemakers, tip electrodes which are configured to make direct
30 contact with the myocardium, have traditionally been used for local sensing. Non-local sensing may be accomplished via various electrode pairs of an implantable pacemaker or

defibrillator, including transvenous, endocardial, and epicardial electrodes (i.e., intrathoracic electrodes), and/or subcutaneous, non-intrathoracic electrodes, including can, header, and indifferent electrodes, and subcutaneous array or lead electrodes (i.e., non-intrathoracic electrodes). For example, electrode pairs suitable for non-local sensing
5 include RV-ring to RV-coil, RV-ring to SVC-coil, RV-ring to RA-ring, or may include sensing between two can electrodes, between a can electrode and an indifferent electrode, or between a can or indifferent electrode and a ring or coil electrode. An electrode pair, as used herein, refers to at least two electrodes, wherein each electrode of the pair may comprise multiple electrodes and/or multiple electrode elements used for sensing.

10 In some situations, the particular placement of a ring, coil, or other electrode configured for non-local sensing may cause the electrode to make direct contact with the myocardium. In these situations, unintentional local sensing is apparent from the cardiac waveform morphology and use of the electrode in conjunction with pacing parameter determination via non-local sensing in accordance with embodiments of the present
15 invention may be avoided.

Embodiments of the invention are directed to systems and methods for timing the delivery of one or more pacing pulses based on sensed signals from local and non-local cardiac sites. The flow diagram of Figure 1A illustrates a method of determining pacing timing in accordance with embodiments of the invention. At least one local cardiac signal
20 is sensed 110 from at least one local cardiac site. At least one non-local cardiac signal is sensed 115 from at least one non-local site. A temporal relationship is determined 120 between the timing of a feature of the local signal associated with activation of a heart chamber and the timing of a feature of the non-local signal associated with activation of the heart chamber. Pacing is delivered 125 based on the temporal relationship.

25 According to some implementations, the local signal feature and the non-local signal feature are detected and the temporal relationship is determined as the interval of time between the local and non-local features. The flow diagram of Figure 1B illustrates a method for determining a pacing interval, such as an atrioventricular delay, based on the time interval between features of the local and non-local signals in accordance with
30 various embodiments. Local and non-local cardiac signals are sensed 141. A feature of the non-local signal associated with activation of a heart chamber is detected 143. A

feature of the local signal associated with activation of the heart chamber is detected 145. The interval between the timing of the non-local signal feature and the timing of the detected local signal feature is determined 147. A pacing interval is determined 149 based on the interval between the non-local and local signal features.

5 In some implementations, both local and non-local signals are sensed and pacing is triggered based on detection of either a non-local signal feature or a local signal feature. For example, detection of a non-local feature may trigger pacing to one or more heart chambers. A feature of the local signal, which may be more reliably detected than the non-local feature, may be used to trigger pacing in the absence of detection of the non-local
10 signal feature. In one example, sensing of both local and non-local signals is employed, but a feature of only one of the cardiac signals is detected and used to trigger the pacing.

An embodiment directed to trigger pacing that relies on sensing both local and non-local signals is illustrated in the flow diagram of Figure 1C. Both local and non-local signals are sensed 151. Detection 153 of a non-local signal feature associated with
15 activation of a heart chamber triggers 157 delivery of a pacing pulse. In this embodiment, the non-local signal feature which is associated with activation of a heart chamber occurs prior to the local signal feature associated with activation of the heart chamber. If a non-local feature is not detected 153 and a local feature is detected 154, the system determines that activation has occurred, but the non-local feature was not detected 155. Pacing is
20 triggered 156 based on the detected local signal feature. If no activation is detected from either the local or non-local signals, a backup pace may be delivered 159.

In various implementations, the delivery of one or more pacing pulses may be timed based on a pacing timing interval such as an atrioventricular timing interval, an interatrial timing interval and/or an interventricular timing interval. An atrioventricular
25 pacing delay is a timing interval between an atrial sensed or paced event and delivery of a ventricular pace. The atrial event may be a right atrial event or a left atrial event and the ventricular pace may be a right ventricular pace or a left ventricular pace. An interatrial pacing delay is a timing interval between a sensed or paced event in one atrium and a pace delivered to the other atrium. An interventricular pacing delay is a timing interval between
30 a sensed or paced event in one ventricle and a pace delivered to the other ventricle. Pacing pulses may be delivered to each of the electrodes in a timed sequence according to

interchamber pacing delays that improve the contractile function. Timing the delivery of pacing pulses based on non-local sensing is particularly advantageous for cardiac resynchronization therapy because non-local sensing provides information about left chamber (e.g., left atrial) contractions without the need for local placement of left chamber sense electrodes.

Figures 2A-2B illustrate local and non-local cardiac signals which may be used for timing the delivery of pacing pulses. Figures 2A and 2B illustrate cardiac signals 201, 202 sensed from a local site and a non-local site, respectively. In some implementations the local 201 and non-local 202 signals are sensed simultaneously. The portion of the cardiac signals 201, 202 representing activation of the atrial muscle fibers is referred to as a P-wave 211, 212. Activation of the ventricular muscle fibers is collectively represented by Q 221, 222, R 231, 232, and S 241, 242 waves of the cardiac signals 201, 202. The Q 221, 222, R 231, 232, and S 241, 242 waves are typically referred to collectively as the QRS complex, which is a well-known morphologic feature of electrocardiograms. Finally, the portion of the signal representing repolarization of the ventricular muscle fibers is known as a T wave 251, 252. Between contractions, the cardiac signal returns to an isopotential level during the T-wave 251, 252.

The cardiac signal 201 illustrated in Figure 2A is typical of a local signal sensed using an electrode in contact with the myocardium. The cardiac signal 202 illustrated in Figure 2B is typical of a non-local cardiac electrical signal, which is effectively a superposition of a number of activation signals. The cardiac signal 202 may be obtained via a non-local electrode pair electrically coupled to, but not in direct contact with, the myocardium.

Non-local sensing is particularly useful, for example, because it provides information about activation of the left atrium. Cardiac pacemakers providing resynchronization therapy typically include one or more electrodes in the right atrium for local sensing of right atrial activation signals. An atrioventricular delay (AVD) is initiated upon sensing an intrinsic depolarization of the right atrium or a right atrial pace. One or both ventricles are paced following the AVD. In some current devices, the conduction time delay resulting from paced or sensed atrial beats is accounted for by setting a fixed AVD based on population statistics and initiated by local right atrial sensing. A fixed

AVD based on local right atrial sensing alone may not be appropriately timed to take into account a particular patient's interatrial conduction time. Further, if the atrium is paced, the atrial pacing results in a non-physiologic activation sequence that may further prolong activation of the atrium. If the fixed AVD is inappropriately programmed, the
5 hemodynamic synchronization between atrial and ventricular contractions is sub-optimal.

The non-local signal provides information about left atrial activation timing and may be used in conjunction with the local signal to determine an AVD tailored to a particular patient and/or tailored to a particular type of pacing cycle. A pacing cycle in which one or both atria are paced may use an AVD having a different duration than a
10 pacing cycle in which the atria are not paced. As described herein, local and non-local sensing may be used to provide a dynamically adjustable AVD. In some implementations, the duration of the AVD may be determined based at least in part on the timing of the end of the non-local P-wave. In some implementations, the AVD may be determined based on the temporal relationship between the timing of the end of the local P-wave and the timing
15 of a feature of the non-local P-wave.

Embodiments of the present invention provide pacing timing optimization approaches that are patient specific and allow dynamic adjustment of interchamber pacing delays. According to various embodiments, timing information associated with features of
20 the local and non-local signals may be used to determine pacing timing delays. For example, timing intervals may be based on the relationship between feature points, such as the start, end, or peak value, of the local signal and feature points, such as the start, end, or peak value, of the non-local signal. The timing of the delivery of pacing pulses may be based on widths of various features. In one implementation, the length of the AVD, which
25 determines the timing of the delivery of a ventricular pacing pulse, is related to the P-wave width of the non-local signal. The non-local P-wave width is representative of the conduction delay between the right and left atria. Generally, a relatively larger P-wave width indicates a longer conduction delay in the activation signals propagating between the atria. Using the non-local P-wave width in the determination of the AVD allows for
30 synchronous atrioventricular pacing so that pacing pulses are delivered to one or both

ventricles at an optimal time following the atrial contraction. Improved timing of ventricular pacing improves cardiac pumping action and increases output.

In some configurations, adjustment of the pacing timing intervals may be performed for each cardiac cycle on a beat by beat basis. In some configurations, one or more pacing timing intervals may be determined using data collected from local and non-local signals of previous cardiac cycles.

One example, illustrated by the graph of Figure 3 and the flow diagram of Figure 4, involves the beat by beat adjustment of AVD based on P-waves detected from both the local 301 and non-local 302 signals of each cardiac cycle. The device senses for a P-wave 311 on the local signal 301 and initiates an AVD 380 if the local P-wave 311 is detected. The device detects the end 313 of the non-local P-wave 312. Following a predetermined interval from the end 313 of the non-local P-wave 312, the AVD 380 ends and a pacing pulse 390 is delivered to a ventricle. In some embodiments, the AVD 380 is dynamically adjusted beat by beat using the process described above based on the detection of the local P-wave 311 and the timing of the end 313 of the non-local P-wave 312.

Beat by beat adjustment of the AVD based on local and non-local P-waves is further illustrated by the flowchart of Figure 4A. The device senses for a P-wave on the local signal. If the local P-wave is detected 412, then the AVD delay is started 415. If a timeout interval is exceeded 420 while sensing for the local P-wave, then the atrium is paced 425.

The device senses 430 for the end of a non-local P-wave. If the non-local P-wave is detected 435, then the AV delay ends 440 after a predetermined time delay 437 and a pacing pulse is delivered 445 to one or both ventricles. The predetermined time delay may be zero or may be greater than zero and less than about 300 msec, for example. Selection of the predetermined time delay may be based on clinical data or on individualized data from the patient, such as interchamber conduction data. Particularly for CHF patients, the predetermined time delay may be selected to produce optimal cardiac pumping function and/or reduce the symptoms of CHF. The predetermined time delay may be adjustable based on acute or chronic factors, such as the patient's metabolic demand or disease progression.

If, while waiting for the end of the non-local P-wave, a timeout interval is exceeded 450, then the AVD ends 440 and a pacing pulse is delivered 445 to one or both ventricles.

The graph of Figure 5 illustrates a method for determining the AVD according to another embodiment. In this embodiment, local 501 and non-local 502 signals are sensed for one or more cardiac cycles. The system searches for a feature point 581 of the local P-wave 511, such as the start, end, or peak of the local P-wave. In the example illustrated in Figure 5, the system searches for the beginning 581 of the local P-wave. The system searches a feature point of the non-local P-wave 512, such as the end 513 of the non-local P-wave 512. The interval 550 between the beginning 581 of the local P-wave 511 and the end 513 of the non-local P-wave 512 is measured for one or multiple cardiac cycles. The AVD is determined based on the measured intervals 550. For example, the AVD may be determined based on a median, mean, or weighted average of the measured intervals. The device uses the AVD for subsequent cardiac cycles. Periodically, the AVD may be updated using the process described above.

In some embodiments, a number of AVDs may be determined as described in Figure 5 for different heart rates. The AVDs may be indexed by rate and stored. If a particular heart rate is detected, an AVD corresponding to the particular rate may be selected for use. Different AVDs may be determined for intrinsic and paced beats. Use of both the local and non-local signals for determination of the AVD as described herein produces pacing that is consistent for intrinsic and paced beats. The determination of AVD based on non-local sensing provides the ability to react to cases in which the atrial lead position results in shorted paced P-waves, as has been shown in lower atrial septal pacing.

In some embodiments, timing the delivery of pacing pulses involves triggering pacing of a heart chamber or contralateral heart chambers based on one or more signal features. This implementation is particularly useful for triggered ventricular pacing in patients having prolonged interatrial conduction times and ventricular conduction abnormalities. In these patients, activation of the ventricles may precede sensed activation at the local ventricular sense electrode. As described more fully below, the non-local signal may be used to detect the first activation of the ventricles. Biventricular pacing may be triggered based on the first ventricular activation detected via the non-local signal.

Biventricular trigger pacing as provided by this embodiment uses intrinsic conduction to activate the septum and promote fusion between intrinsically conducted activation and paced ventricular activity to achieve optimized cardiac performance for individual patients.

The flowchart of Figure 6 illustrates ventricular pacing triggered by a feature point
5 of the non-local signal with backup pacing implemented using a pacing timing delay initiated by a local signal. Although the example of Figure 6 is directed to triggered ventricular pacing, a similar process may be implemented for triggered atrial pacing. The device senses 610 signals from a local ventricular site and a non-local site. If the initiation of a QRS complex is detected 615 on the non-local signal, pacing is triggered 620 to one
10 or both ventricles. The ventricles are paced using a first interventricular delay IVD1. If the initiation of the QRS complex is not detected 615, and a timeout has occurred 625, then an alternate process for timing ventricular pacing is used. If the QRS complex has been detected 630 on the local right ventricular signal, then the left ventricle is paced 635 using IVD2. If the right ventricular QRS complex is not detected 640 following a timeout
15 period, then the right and left ventricles are paced 645 using IVD3.

In some embodiments, IVD1, IVD2, and IVD3 may have the same duration. In other embodiments, one or more of the IVDs used in the above example may be selected to achieve optimal cardiac output for the particular pacing timing situation. The IVDs may be determined, for example, from previously detected local and/or non-local signals. The
20 IVDs may be determined based on the QRS complex width of the non-local signal, or the interval between a local signal feature point and a non-local signal feature point, or by other methods.

A wide variety of implantable cardiac stimulation devices may be configured to sense local and non-local signals and time the delivery of pacing pulses in accordance with
25 the present invention. A non-limiting, representative list of such devices includes pacemakers, cardioverters, defibrillators, resynchronizers, and other cardiac therapy delivery devices. These devices may be configured with a variety of electrode arrangements, including transvenous, endocardial, and epicardial electrodes (i.e., intrathoracic electrodes), and/or subcutaneous, non-intrathoracic electrodes, including can,
30 header, and indifferent electrodes, and subcutaneous array or lead electrodes (i.e., non-intrathoracic electrodes). A cardiac therapy device implemented in accordance with the

present invention may incorporate one or more of the electrode types identified above and/or combinations thereof to sense local and non-local signals.

Referring now to Figure 7, the implantable device illustrated in Figure 7 is an embodiment of a therapy device 700 that may be used to time the delivery of cardiac
5 pacing pulses based on local and non-local sensing in accordance with embodiments of the invention. In this example, the therapy device 700 includes a pulse generator 705 electrically and physically coupled to an intracardiac lead system 710.

Portions of the intracardiac lead system 710 are inserted into the patient's heart. The intracardiac lead system 710 includes one or more electrodes configured to sense
10 electrical cardiac activity of the heart and deliver electrical stimulation to the heart. Additionally, the cardiac electrodes and/or other sensors may be used to sense the patient's transthoracic impedance, and/or sense other physiological parameters, such as cardiac chamber pressure or temperature. The electrodes shown in Figure 7 illustrate one possible arrangement of electrodes. Many other electrode arrangements, including intracardiac
15 and/or subcutaneous intrathoracic and non-intrathoracic electrodes, may be used to achieve local and non-local sensing and are considered to fall within the scope of the invention. The lead system 710 may include wired and/or wirelessly coupled electrodes. In wireless configurations, sensed signals from the electrodes are wirelessly communicated to the pulse generator 705 and/or may also be communicated wirelessly to a patient-external
20 device.

Portions of the housing 701 of the pulse generator 705 may optionally serve as one or multiple can or indifferent electrodes. The housing 701 is illustrated as incorporating a header 789 that may be configured to facilitate removable attachment between one or more leads and the housing 701. The housing 701 of the pulse generator 705 may include one or
25 more can electrodes 781b, and 781c. The header 789 of the pulse generator 705 may include one or more indifferent electrodes 781a. The housing 701 and/or header 789 may include any number of electrodes positioned anywhere in or on the housing 701 and/or header 789. In various configurations, one or more housing/header electrodes 781a-781c may be used as one electrode of an electrode pair 781a-781c providing non-local sensing and another one or more housing/header electrodes 781a-781c may be used as the other
30 electrode of the electrode pair. In other embodiments, one or more housing/header

electrodes 781a-781c may be used as one electrode of a non-local electrode pair providing non-local sensing and one or more intracardiac electrodes such as the SVC coil 741, RA ring 751, RV coil 742, RV ring 756, and/or LV ring electrode 754 may be used as the other electrode of the non-local electrode pair. Local signals may be sensed via tip electrodes
5 configured for local sensing such as the RA tip electrode 752, the RV tip electrode 753 and the LV distal electrode 755.

Communications circuitry is disposed within the housing 701 for facilitating communication between the pulse generator 705 and a patient-external device, such as an external programmer or advanced patient management (APM) system, for example. The
10 communications circuitry may also facilitate unidirectional or bidirectional communication with one or more implanted, external, cutaneous, or subcutaneous physiologic or non-physiologic sensors, patient-input devices and/or information systems.

The pulse generator 705 may include circuitry, such as filters, amplifiers, digitizers and/or other signal processing circuitry for useful in sensing local and non-local cardiac
15 signals. The pulse generator may also include circuitry for detecting and/or measuring signal features. Control circuitry for controlling pacing and/or defibrillation/cardioversion therapy and other functions of the pacemaker is enclosed in the housing of the pulse generator 705.

The lead system 710 and pulse generator 705 of the therapy device 700 may
20 incorporate one or more transthoracic impedance sensors that may be used to acquire the patient's respiratory waveform, and/or other respiratory-related information. The transthoracic impedance sensor may include, for example, one or more intracardiac electrodes 741, 742, 751-756 positioned in one or more chambers of the heart. The intracardiac electrodes 741, 742, 751-756 may be coupled to impedance drive/sense
25 circuitry positioned within the housing 701 of the pulse generator 705. Information from the transthoracic impedance sensor and/or an activity sensor may be used to adapt the rate of pacing to correspond to the patient's activity and/or hemodynamic need.

The lead system 710 may include one or more cardiac pace/sense electrodes 751—
756 positioned in, on, or about one or more heart chambers for sensing electrical signals
30 from the patient's heart and/or delivering pacing pulses to the heart. The intracardiac sense/pace electrodes 751—756, such as those illustrated in Figure 7, may be used to sense

and/or pace one or more chambers of the heart, including the left ventricle, the right ventricle, the left atrium and/or the right atrium. The lead system 710 may include one or more defibrillation electrodes 741, 742 for delivering defibrillation/cardioversion shocks to the heart.

5 The pulse generator 705 may include circuitry for detecting cardiac arrhythmias and/or for controlling pacing or defibrillation therapy in the form of electrical stimulation pulses or shocks delivered to the heart through the lead system 710.

10 In some embodiments, the pulse generator 705 may include circuitry for determining interchamber pacing timing intervals, such as AVD and/or IVD, using the local and non-local signals. In other embodiments, the pulse generator 705 may transfer sensed or derived information relevant to the determination of pacing timing to a patient-external device. Following download of the implantably sensed or derived information, determination of pacing timing intervals may be made by the patient-external device or may be made by a human analyst. Following pacing timing determination, the pacing
15 timing intervals may be transferred to the therapy device 700 and used to control pacing pulses delivered to the heart to effect a pacing therapy for enhancing cardiac function.

20 Figure 8 is a block diagram depicting various components of a system that may be used to deliver pacing therapy with pacing timing implemented in accordance with embodiments of the invention. The components, functionality, and configurations depicted are intended to provide an understanding of various features and combinations of features that may be incorporated in such a system. It is understood that a wide variety of device configurations are contemplated, ranging from relatively sophisticated to relatively simple designs. As such, particular configurations may include some components illustrated in Figure 8, while excluding other components. In certain embodiments, the arrangement of the
25 functional blocks may vary from the arrangement depicted.

30 Figure 8 illustrates functionality for timing delivery of pacing pulses based on the use of local and non-local signals. In some embodiments, the functionality may be incorporated into an implantable device. In other embodiments, the functionality may be incorporated in the patient-external programmer. In yet other embodiments, the functionality may be divided between a patient implantable device and a patient external device.

In some implementations, the control processor 840 may execute a relatively sophisticated algorithm that automatically determines pacing the control processor may format information for display to allow a human analyst to review information from local and non-local signals to make a determination regarding optimal timing for pacing.

5 Illustrated in Figure 8 is a therapy system 800 having control processor 840 coupled to appropriate memory (volatile and/or non-volatile) 845, it being understood that any logic-based control architecture may be used. The control processor 840 is also coupled to circuitry and components configured to sense electrical signals produced by the heart and to deliver electrical stimulation energy to the heart under predetermined
10 conditions to treat cardiac arrhythmias and/or other cardiac conditions. The electrical energy delivered by the therapy device 800 may be in the form of low energy pacing pulses or high-energy pulses for cardioversion or defibrillation.

Cardiac signals are sensed using cardiac electrodes 805, including local 810 and non-local electrodes 815. A switch matrix 825 is employed to selectably couple various
15 combinations of the cardiac electrodes 805 to the sensing circuitry 820. The sensed cardiac signals are received by sensing circuitry 820, which includes circuitry and for amplifying, filtering and/or digitizing the local and non-local signals. The sensed cardiac signals may optionally be processed by noise reduction circuitry (not shown), which may reduce noise and or increase the signal to noise ratio (SNR) of the signals before signals
20 are sent to the control processor 840.

The control processor 840 may include arrhythmia detection circuitry such as a signal processor that coordinates analysis of the sensed cardiac signals and/or other sensor inputs to detect cardiac tachyarrhythmia. Rate based and/or morphological discrimination algorithms may be implemented by the control processor 840 to detect and verify the
25 presence and severity of an arrhythmic episode. If arrhythmia is detected, the therapy control processor 840 may coordinate delivery of an appropriate therapy, such as anti-tachyarrhythmia pacing therapy (ATP), cardioversion, and/or defibrillation via the defibrillation/cardioversion circuitry 835 to terminate or mitigate the arrhythmia.

The therapy device 800 incorporates cardiac pacing capability in addition to, or to
30 the exclusion of, cardioversion and/or defibrillation capabilities. As is shown in Figure 8, the therapy device 800 includes pacing therapy circuitry 830 that is coupled to the therapy

control processor 840 and to the electrodes 805 via the switch matrix 825. Under the control of control processor 840, the pacing therapy circuitry 830 delivers pacing pulses to the heart in accordance with a selected pacing therapy, such as a pacing therapy using pacing timing intervals determined by the approaches described herein.

5 Control signals, developed in accordance with a pacing regimen by pacemaker circuitry within the therapy control processor 840, are initiated and transmitted to the pacing therapy circuitry 830 where pacing pulses are generated. A pacing therapy, such as those discussed and incorporated herein, may be modified by the therapy control processor 840. Pacing therapy may be implemented to terminate or mitigate cardiac
10 tachyarrhythmia, to provide a heart rate that ensures sufficient blood flow, and/or to enhance synchronization of the heart chamber contractions.

The sensing circuitry 820 is configured to sense local and non-local cardiac electrical signals via the electrodes 810, 815 and to communicate cardiac signal information to the control processor 840. The control processor 840 may also be
15 configured to receive signals from one or more additional physiologic and/or non-physiologic sensors 860. The additional physiological signals and/or non-physiological signals may be used in connection with various diagnostic, therapeutic or monitoring implementations. For example, the therapy device 800 may include sensors or circuitry for detecting respiratory system signals, cardiac system signals, and/or signals related to
20 patient activity or metabolic demand. The therapy control processor 840 may adapt the pacing rate based on the patient's sensed metabolic demand.

Cardiac signals sensed via the local and/or non-local electrode pairs 810, 815 are used by the control processor 840 to determine timing for pacing pulses as described herein. For example, the control processor 840 may analyze the sensed signals to detect
25 signal features. The control processor 840 may determine interchamber timing delays, such as AVD and/or IVD, for pacing therapy based on the signal features. The control processor 840 may implement trigger pacing and may deliver backup pacing based on local and non-local sensing.

Memory circuitry 845 of the therapy device 800 contains parameters for operating
30 in various monitoring, defibrillation, and pacing modes. The memory circuitry 845 may also be configured to store historical data, which may be used for various purposes and

transmitted to an external receiving device 855 as needed or desired. For example, in certain embodiments, the memory circuitry 845 may store formulas and/or tables used in connection with determining pacing timing. The formulas and/or tables may be indexed according to heart rate.

5 Communications circuitry 850 is coupled to the control processor 840. The communications circuitry 850 allows communication between devices, such as patient-external devices 855 and patient-implantable devices. In one configuration, the communications circuitry 850 and the patient-external device 855 use a wire loop antenna and a radio frequency telemetric link, as is known in the art, to receive and transmit signals
10 and data between the patient-external device 855 and communications circuitry 850. In this manner, programming commands and data may be transferred to the control processor 840 from the patient-external device 855 during and after implant. Using a patient-external programmer, a physician is able to set or modify various parameters used by the therapy control processor 850. For example, a physician may set or modify parameters
15 affecting monitoring, detection, pacing, and defibrillation functions of the therapy control processor 840.

 In certain embodiments, the control processor 840 transmits information for determination of pacing timing to the patient-external device 855. The information may include, for example, cardiac electrical signals obtained via local and/or non-local sensing,
20 markers indicating the timing of certain features or points, measured characteristics or features of the signals, and/or other information. The patient-external device 855 may use the transmitted information to determine pacing timing intervals or may format and display information from local and non-local sensing to facilitate the determination of pacing timing intervals by a human analyst.

25 Processes for timing the delivery of pacing pulses based on cardiac signals obtained via local and non-local sensing in accordance with embodiments of the invention may be implemented by an implantable device, by a patient-external device, such as a programmer or advanced patient management system, or by a manually implementable procedure, such as by using a printed table lookup to compute the optimal values, and/or
30 by any combination of these techniques.

In one embodiment, the patient-external programmer 855 communicates with the control processor 840 over a telemetry link and receives either raw electrogram data, markers corresponding to particular sensed events, and/or measurements of intervals between sensed events or feature widths as computed by the implantable device. The external programmer 855 may then compute optimal settings for pacing timing intervals which are either transmitted to the control processor 840 for immediate reprogramming or presented to a clinician operating the external programmer as recommendations.

In another embodiment, the external programmer 855 may present the data, markers, and/or measurements to a human analyst who then programs the control processor 840 in accordance with an algorithm. In yet a further embodiment, determination of the pacing timing may be fully automatic and performed by an implantable therapy device.

CRT patients who are paced using inappropriate pacing timing delays may not benefit by CRT therapy. One goal of CRT is to optimize the LA/LV timing in order to increase atrioventricular synchrony and thus enhance cardiac performance. The use of RA local signals to determine timing intervals is hindered by the lack of LA information available using RA local sensing alone. The difference in activation sequences between intrinsic and paced activity further complicates achieving optimal atrioventricular synchrony due to variable patient physiology and pathology. Non-local sensing of signals provides additional information useful for determining pacing timing that promotes atrioventricular synchrony and improved cardiac performance.

Various modifications and additions can be made to the preferred embodiments discussed hereinabove without departing from the scope of the present invention. Accordingly, the scope of the present invention should not be limited by the particular embodiments described above, but should be defined only by the claims set forth below and equivalents thereof.

CLAIMS

What is claimed is:

- 5 1. A method for delivery of pacing therapy, comprising:
sensing, using body-implantable electrodes, at least one local cardiac electrical
signal and at least one non-local cardiac electrical signal;
sensing for a feature of the local signal corresponding to activation of a heart
chamber;
10 sensing for a feature of the non-local signal corresponding to the activation of the
heart chamber; and
timing delivery of one or more pacing pulses based on a temporal relationship
between timing of the feature of the local signal and timing of the feature of the non-local
signal.
15
2. The method of claim 1, wherein:
sensing the local signal comprises sensing, for a cardiac cycle, the local signal;
sensing the non-local signal comprises sensing, for the cardiac cycle, the non-local
signal; and
20 timing delivery of the pacing pulses comprises timing delivery of the pacing pulses
for the cardiac cycle.
3. The method of claim 1, wherein timing delivery of the pacing pulses comprises
determining an atrioventricular delay based on the temporal relationship between the local
25 feature timing and the non-local feature timing.
4. The method of claim 1, wherein:
sensing the local cardiac signal comprises sensing from a local atrial site;
30 sensing for the local signal feature comprises sensing for a local P-wave;

sensing for the non-local signal feature comprises sensing for a non-local P-wave;
and

timing the delivery of the pacing pulses comprises determining an atrioventricular
delay based on the temporal relationship between the local P-wave and the non-local P-
5 wave.

5. The method of claim 1, wherein:

sensing the local cardiac signal comprises sensing from a local atrial site;

sensing for the local signal feature comprises sensing for a local P-wave;

10 sensing for the non-local signal feature comprises sensing for a non-local P-wave;
and

timing the delivery of the pacing pulses comprises:

initiating an atrioventricular delay based on the detection of the local P-
wave; and

15 ending the atrioventricular delay based on the detection of the non-local P-
wave.

6. The method of claim 1, wherein timing the delivery of the pacing pulses comprises:
triggering delivery of a pacing pulse if the non-local feature is detected; and
20 triggering delivery of the pacing pulse based on the local feature if the non-local
feature is not detected.

7. The method of claim 6, wherein:

triggering delivery of the pacing pulse if the non-local feature is detected comprises

25 triggering delivery of an atrial pacing pulse if a non-local P-wave is detected; and

triggering deliver of the pacing pulse comprises triggering deliver of the atrial
pacing pulse based on a local P-wave.

8. The method of claim 6, wherein:

triggering delivery of the pacing pulse if the non-local feature is detected comprises triggering delivery of a ventricular pacing pulse if a non-local QRS complex is detected; and

- triggering delivery of the pacing pulse based on the local feature comprises
- 5 triggering delivery of the ventricular pacing pulse based on a local QRS complex if the non-local QRS complex is not detected.

9. An implantable cardiac rhythm management device, comprising:
- a plurality of implantable electrodes electrically coupled to the heart, at least a first
- 10 pair of the plurality of electrodes configured to sense a local cardiac signal and at least a second pair of the plurality of electrodes configured to sense a non-local cardiac signal;
- sense circuitry coupled to the first and second electrode pairs and configured to sense a local cardiac signal via the first electrode pair and a non-local cardiac signal via the second electrode pair;
- 15 detection circuitry configured to detect a feature of the local signal associated with activation of a heart chamber and to detect a feature of the non-local signal associated with activation of the heart chamber; and
- a control processor configured to time delivery of one or more pacing pulses based on a temporal relationship between timing of the local signal feature and timing of the
- 20 non-local signal feature.

10. The device of claim 9, wherein at least one electrode of the second pair of electrodes comprises a ring electrode.
- 25 11. The device of claim 9, wherein at least one electrode of the second pair of electrodes comprises a defibrillation coil.
12. The device of claim 9, wherein the at least one electrode of the second pair of electrodes comprises a subcutaneous, non-intrathoracic electrode.
- 30 13. The device of claim 9, wherein:

the local signal feature comprises a local P-wave;
the non-local signal feature of the comprises a non-local P-wave; and
the control processor is configured determine an atrioventricular delay based on the
temporal relationship between the timing of the local P-wave and the timing of the non-
5 local P-wave, the atrioventricular delay used to time delivery of the one or more pacing
pulses.

14. The device of claim 13, wherein the control processor is configured to determine
the atrioventricular delay based on the temporal relationship between a beginning, end, or
10 peak timing of the local P-wave and a beginning, end, or peak timing of the non-local P-
wave.

15. The device of claim 9, wherein the control processor is configured to trigger pacing
based on the timing of the non-local signal feature if the non-local signal feature is
15 detected and to trigger pacing based on the timing of the local signal feature if the non-
local signal feature is not detected.

16. The device of claim 9, wherein delivery of the pacing pulses comprises delivery of
an atrioventricular synchronous pacing therapy.

20

17. The device of claim 9, wherein delivery of the pacing pulses comprises delivery of
a bradycardia pacing therapy.

18. The device of claim 9, wherein the deliver of the pacing pulses comprises delivery
25 of a resynchronization pacing therapy.

19. A system for delivery of pacing therapy, comprising:
a first pair of body-implantable electrodes configured to sense a local cardiac
signal;
30 a second pair of body-implantable electrodes configured to sense a non-local
cardiac signal;

means for detecting a feature of the local signal related to activation of a cardiac chamber;

means for detecting a feature of the non-local signal related to activation of the cardiac chamber; and

5 means for timing delivery of one or more pacing pulses based a temporal relationship between timing of the local feature and timing of the non-local feature.

20. The system of claim 19, further comprising means for determining an atrioventricular delay based on the temporal relationship.

10

21. The system of claim 19, further comprising means for implementing triggered pacing based on the temporal relationship between the timing of the local signal feature and the timing of the non-local signal feature.

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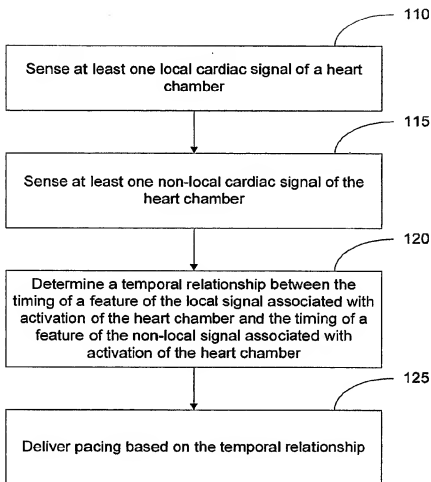


Figure 1A

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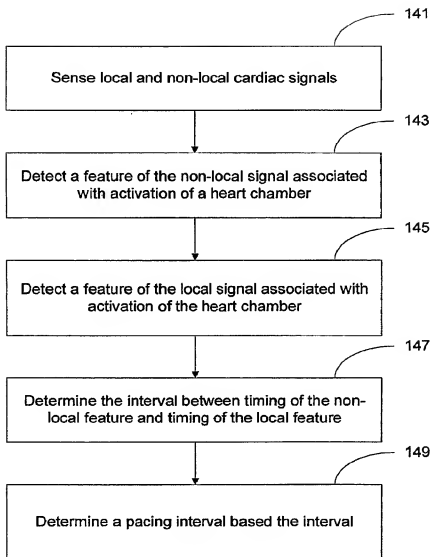


Figure 1B

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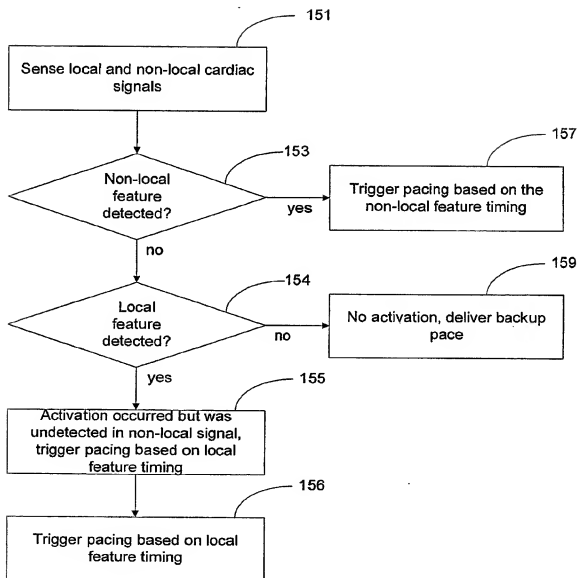


Figure 1C

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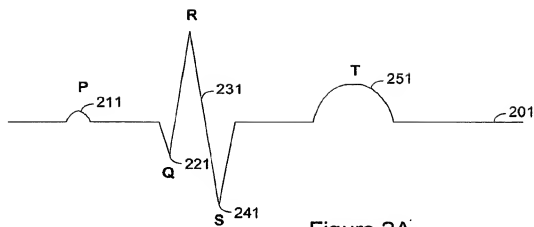


Figure 2A

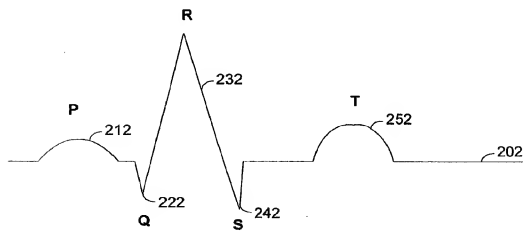


Figure 2B

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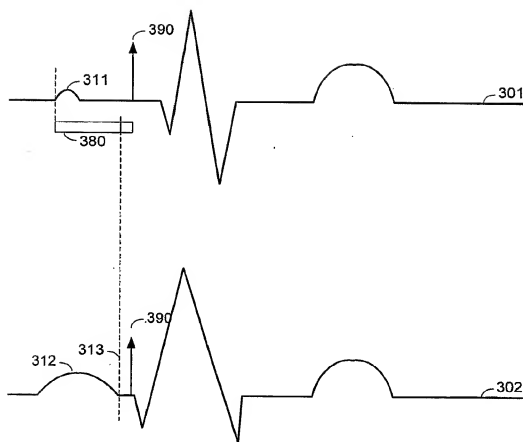
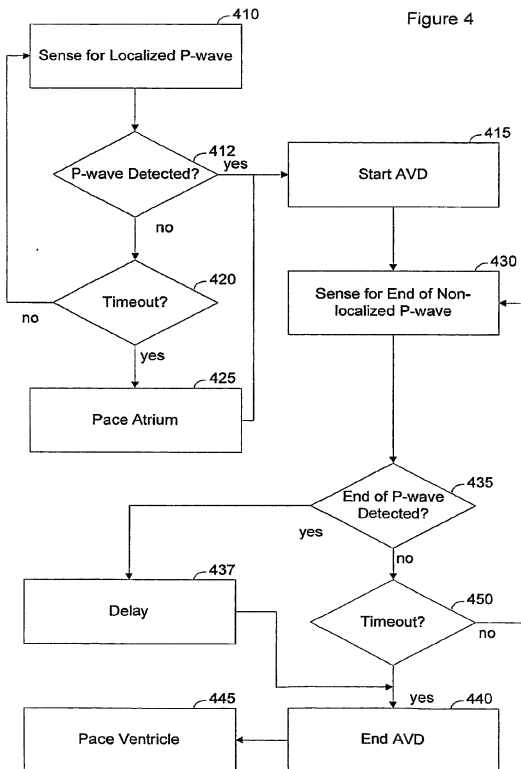


Figure 3

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Figure 4



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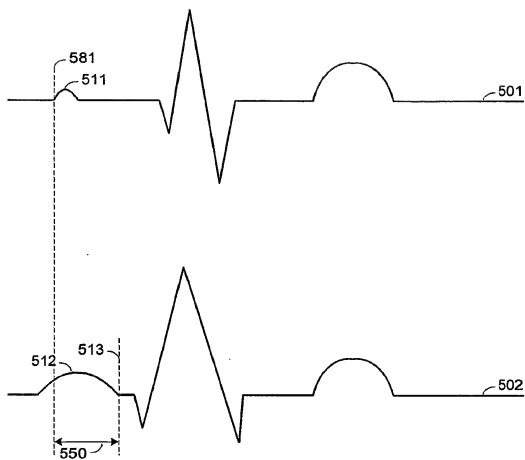
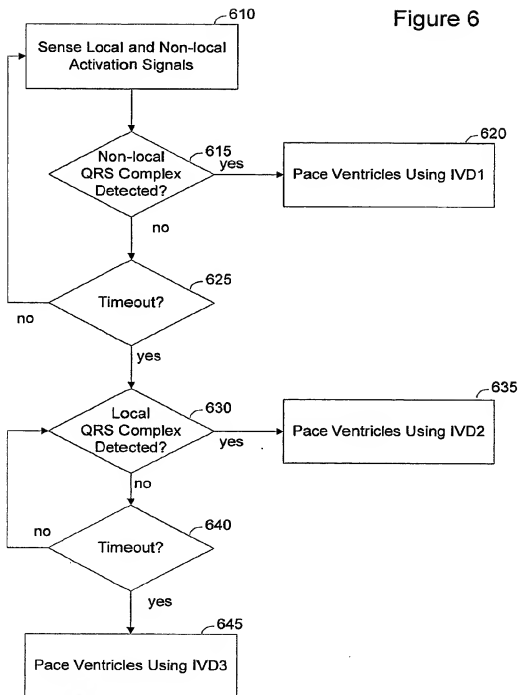


Figure 5

Figure 6



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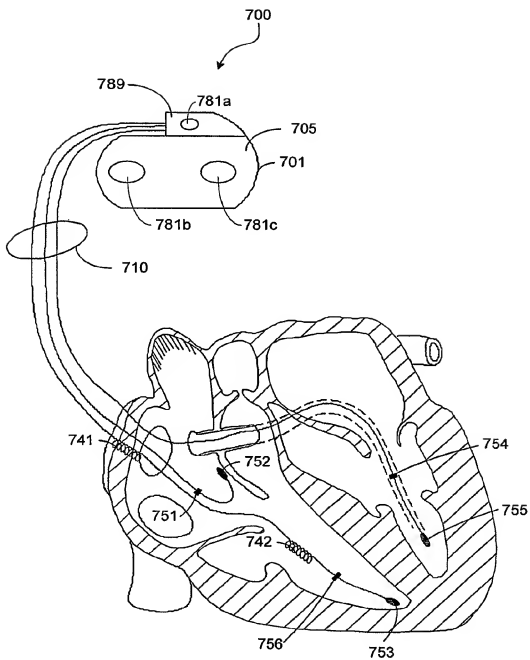


Figure 7

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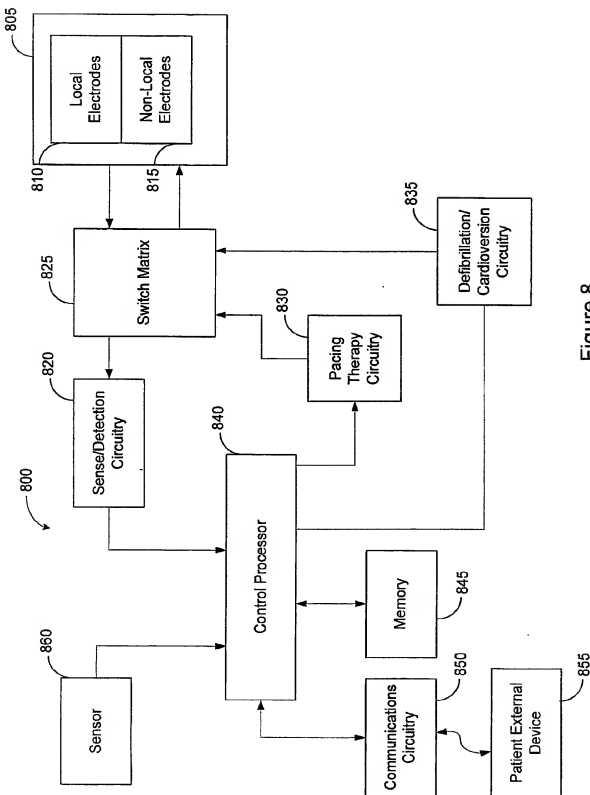


Figure 8